

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Marc Peters-Golden *et al.*

Serial No.: 09/291,656

Group No.: 1653

Filed: 03/03/1999

Examiner: Carlson, K.

Entitled: **Administration Of Products Of The 5-Lipoxygenase Metabolic Pathway To Enhance Antimicrobial Defense**

**APPEAL BRIEF
APPEAL NO.:**

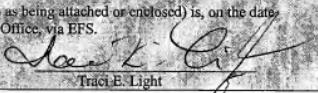
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Dated: August 18, 2008


Traci E. Light

BPAI:

This Brief is in furtherance to the Notice of Appeal mailed by the Applicant on June 23, 2008 regarding the Final Office Action mailed March 10, 2008. It is believed that the submission is timely and no extensions of time are needed.

This Brief is transmitted as a single copy as per the amended rules. [37 CFR § 41.37(a).]

This Brief contains these items under the following headings and in the order set forth below [37 CFR § 1.192(c)]

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I. REAL PARTY IN INTEREST

The real party in interest is the Regents of the University Of Michigan, 3003 South State Street, Ann Arbor, MI 48109-1280.

II. RELATED APPEALS AND INTERFERENCES

There are no related applications pending appeal.

III. STATUS OF CLAIMS

Claims 1-21 are canceled. Claims 22-25 are rejected and are currently appealed. Claim 26 is canceled. Claim 27 is rejected and currently appealed. Claims 28-37 are canceled. Claim 38 is rejected and currently appealed.

IV. STATUS OF AMENDMENTS

All amendments in the case have been entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The independent claim (Claim 22) recites an aerosol (pg 53 ln 2-3) for the treatment of a microbial infection (pg 13 ln 17 - pg 15 ln 25) comprising a sterile vehicle (pg 8 ln 28), and a leukotriene (pg 10 ln 18 - pg 13 ln 15), wherein the aerosol comprises a gaseous suspension of fine or liquid particles (*Ex parte Peters-Golden*, pg 3, Appeal 2007-1145 (2007). Dependent Claim 23 recites that the leukotriene is leukotriene B₄. (pg 5 ln 4-5). Dependent Claim 24 recites that the leukotriene is a cysteinyl leukotriene. (pg 5 ln 4-6). Dependent Claim 25 recites that the cysteinyl leukotriene is leukotriene C₄, leukotriene D₄, and leukotriene E₄ (pg 5 ln 4-6). Dependent Claim 27 recites that the microbiological infection comprises a *Klebsiella pneumoniae* infection. (pg 3 ln 17-19). Dependent Claim 38 recites that the aerosol further comprises an antibiotic. (pg 4 ln 31-35).

VI. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

- A. Whether Claims 22-25 and 27 are properly rejected under 35 USC § 102(e) as allegedly being anticipated by United States Patent No. 5,789,441 To Gosselin et al.
- B. Whether Claim 22 and 38 are properly rejected under 35 USC § 103(a) as allegedly being unpatentable under United States Patent No. 5,789,441 To Gosselin et al.

VII. ARGUMENT

A. The Claims Are Not Anticipated

As the Board is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). This criterion is not met with the Gosselin et al. reference.

1. Independent Claim 22 Is Not Anticipated

The Examiner has provided a new anticipation rejection on the basis that:

Gosselin et al. teach leukotriene LTB₄ in a sterile liquid ...

Final Office Action mailed 03/10/08 [emphasis added]. The Applicants submit that this is an improperly formed rejection, as the Applicants' claims do not recite "a sterile liquid". The Examiner is reminded that in the Applicants' last response, Claim 22 was amended to clarify the claimed embodiment to recite "an aerosol". Gosselin et al. does not disclose "an aerosol", a fact the Examiner has kindly provided by citing the previous Board Decision:

Gosselin et al. does not disclose a solution in the form of a gaseous suspension ...

Final Office Action mailed 03/10/08. Further, the Applicants' previous response provided the Examiner with evidence that the Board also held that the Applicants' specification provides adequate support for an aerosol composition:

The Specifications' description of administering compositions by aerosolization supports Applicants' position that claim 22 defines a composition in aerosol from or in a form suitable for aerosolization (corresponding to Appellants' two definitions of "aerosol"). The Examiner has not disputed the accuracy of Appellants' definition of "aerosol". We therefore interpret claim 22 to be directed to a composition comprising the recited elements, in a form which is either a gaseous suspension of particles or packaged under pressure with a gaseous propellant.

Ex parte Peters-Golden, pg. 3, Appeal 2007-1145 (2007) [emphasis added]. Without question, therefore, the United States Patent Office Board of Appeals clearly held that: i) Gosselin et al. does not teach an aerosol; and ii) the Applicants' specification provides sufficient support to claim an aerosol as a composition. The Examiner, however, apparently disagrees with the Board.

2. Dependent Claim Arguments

The Argument presented below are intended to argue the dependent claim separately.

a. Dependent Claim 23

Gosselin et al. does not disclose 'an aerosol comprising leukotriene B₄'.

b. Dependent Claim 24

Gosselin et al. does not disclose 'an aerosol comprising a cysteinyl leukotriene'.

c. Dependent Claim 25

Gosselin et al. does not disclose 'an aerosol comprising a cysteinyl leukotriene selected from the group consisting of leukotriene C₄, leukotriene D₄, leukotriene E₄'.

d. Dependent Claim 27

Gosselin et al. does not disclose "an aerosol for the treatment of a *Klebsiella pneumonia* infection".

e. Dependent Claim 38

Gosselin et al. does not disclose 'an aerosol comprising an antibiotic'.

3. Conclusion

The Applicants submit that the Examiner has misinterpreted the Board's analysis in the previous appeal and mistakenly asserted the above anticipation rejection. In light of the above explanation, the Applicants respectfully request that the pending anticipation rejection be withdrawn.

B. The Claims Are Not Obvious

To establish a *prima facie* case of obviousness, three basic elements must be present; i) cited art must contain all the claimed elements; ii) the cited art must provide a reasonable expectation of success for the claimed elements; and iii) some motivation must be present to combine the references and/or secondary evidence. *In re Vaeck*, 947 F.2d 488, 493 (Fed Cir. 1991). In the absence of any one of these basic elements, the basis for obviousness fails.

The Applicants respectfully point out that *KSR v Teleflex* has not changed these basic elements. For example, a *prima facie* case of obviousness still must be constructed by using the standard *Graham* factors: i) the scope and content of the prior art must be evaluated; ii) the level of skill in the art must be determined; iii) differences between the scope and content of the prior art and the claimed embodiment must be identified; and iv) it must be determined whether these identified differences are sufficient to establish obviousness. In addition, the *KSR* decision has determined that both the common sense and general knowledge of one having ordinary skill in the art are considered as part of this legal analysis. The USPTO Guidelines admit as such, and provide for the situations wherein obviousness may be found. The Applicants do not believe that the Examiner has meet the burden of these guidelines.

Further, the *KSR* holding only cautioned against a strict application of the "teaching-suggestion-motivation test" such that an explicit teaching is not required to be found within the cited applications. Nevertheless, it is still required to: i) establish *some motivation* to combine the references and/or secondary evidence either explicitly or implicitly, and ii) establish a *prima facie* case of obviousness, wherein the prior art reference (or references when combined) must teach or suggest all the claim limitations. The Applicants submit that the Examiner has not made a *prima facie* case of obviousness.

1. Claim 22

The Examiner has only asserted a single reference (i.e., Gosselin et al.) to support the present obviousness rejection and not provided any additional evidence.

Consequently, the Examiner's *prima facie* case of obviousness clearly stands or falls solely on the basis of the alleged teachings and/or suggestions of Gosselin et al.

a. Gosselin et al. Fails To Teach Or Suggest All The Elements

The Applicants submit that Gosselin et al. fails to support a *prima facie* case of obviousness because the reference does not teach or suggest all the claim limitations. As discussed in Section I (*supra*), Gosselin et al. does not teach 'an aerosol' thereby supporting the Applicants' argument to a lack of obviousness.

In a similar manner, Gosselin et al. does not suggest 'an aerosol'. As the Board has admitted, Gosselin et al. does disclose an aerosol. In the absence of secondary evidence, the Examiner must show that one having ordinary skill in the art of sterile cell culture techniques would have either the common sense or general knowledge to convert the sterile cell culture liquid and/or solution into an aerosol. The Examiner has provided no such evidence, and the Applicants submit that common sense and/or general knowledge among those skilled in the art of using sterile cell culture techniques would not consider using aerosols.

As Gosselin et al. does not teach or suggest all the Applicants' claim limitations, the Applicants respectfully request that the pending rejection be withdrawn.

b. Gosselin et al. Provides No Motivation For An Aerosol

Because the Examiner provides an obviousness rejection based upon a single reference and provides no substantive secondary evidence (i.e., for example, by way of affidavit), the Examiner has admitted that Gosselin et al. provides no motivation for a combination with anything.

Further, if a cell culture solution is replaced with an aerosol, this would result in a condition that is not suitable to Gosselin's purposes. Such a condition is expressly held by the Federal Circuit and embraced by the USPTO as NOT supportive of obviousness:

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

MPEP 2143.01 Section V. Consequently, the Examiner's *prima facie* case of obviousness fails, and the Applicants respectfully request that the pending rejection be withdrawn.

2. Claim 38

The Applicants have shown above that Claim 22 is not obvious in view of Gosselin et al. It is well settled patent law, that nonobviousness of an independent claim is imputed into any and all subsequent dependent claims:

[D]ependent claims are nonobvious if the independent claims from which they depend are nonobvious.

In re Fritch, 972 F.2d 1260, 1266 (Fed. Cir. 1992). As such, the Examiner is respectfully requested to withdraw the pending rejection.

C. Conclusion

The Appellants conclude that the Examiner has not made a *prima facie* case of obviousness. In fact, the Appellants believe that the Examiner has acted in an arbitrary and capricious manner. The Board is reminded that PTO decisions are reviewed using the standard set forth in the Administrative Procedure Act, 5 U.S.C. § 706. *Dickinson v. Zurko*, 527 U.S. 150, 154 (1999). Under that statute, actions are set aside that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Moreover, factual findings are set aside that are unsupported by substantial evidence. *In re McDaniel*, 293 F.3d 1379, 1382 (Fed. Cir. 2002).

Appellants submit that, with due consideration to all these factors discussed above, the patentability of Claims 22-25, 27, and 38 is evident.

For these reasons, the Applicants now appeal because it appears the Examiner has taken an arbitrary and intransigent position. It is submitted that the Examiner's rejections of Claims 22-25, 27, and 38 were erroneous, and reversal of these rejections is respectfully requested.

Respectfully submitted,

Dated: August 18, 2008


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VIII. CLAIMS APPENDIX

22. An aerosol for the treatment of a microbial infection, said aerosol comprising a sterile vehicle and a leukotriene dissolved in said vehicle, wherein said aerosol comprises a gaseous suspension of fine or liquid particles.
23. The aerosol of Claim 22, wherein said leukotriene is leukotriene B₄.
24. The aerosol of Claim 22, wherein said leukotriene is a cysteinyl leukotriene.
25. The aerosol of Claim 24, wherein said cysteinyl leukotriene is selected from the group consisting of leukotriene C₄, leukotriene D₄, and leukotriene E₄.
27. The aerosol of Claim 22, wherein said microbial infection comprises *Klebsiella pneumoniae* infection.
38. The aerosol of Claim 22, wherein said aerosol further comprises an antibiotic.

IX. EVIDENCE APPPENDIX

(No attachments are required for this Brief).

X. RELATED PROCEEDINGS APPENDIX

(No attachments are required for this Brief)